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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/292,437 04/15/99 SCHNEEWIND

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EXAMINER

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HM22/0723

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ART UNIT	PAPER NUMBER
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1645

19

DATE MAILED:

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	Application No. <b>09/292,437</b>	Applicant(s) <b>Schneewind et al</b>
	Examiner <b>Mark Navarro</b>	Art Unit <b>1645</b>

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1)  Responsive to communication(s) filed on \_\_\_\_\_
- 2a)  This action is FINAL.      2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

#### Disposition of Claims

- 4)  Claim(s) 1-97 is/are pending in the application.
- 4a) Of the above, claim(s) 1-7 and 26-97 is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) 8-25 is/are rejected.
- 7)  Claim(s) \_\_\_\_\_ is/are objected to.
- 8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11)  The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved.
- 12)  The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- 13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) All b) Some\* c) None of:
1.  Certified copies of the priority documents have been received.
  2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

- 15)  Notice of References Cited (PTO-892)      18)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16)  Notice of Draftsperson's Patent Drawing Review (PTO-948)      19)  Notice of Informal Patent Application (PTO-152)
- 17)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). 7      20)  Other: \_\_\_\_\_

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## **DETAILED ACTION**

### ***Election/Restriction***

1. Applicant's election with traverse of Group II, claims 8-25, and nucleotide sequences encoding the protein of SEQ ID NO: 3 (Paper number 18) received on May 21, 2001 is acknowledged. The traversal is on the grounds that according to MPEP 803, if the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions. The argument that the restriction is improper because the application can be searched without serious burden is not found persuasive. It is the Examiner's position that it would be an undue burden to search all Groups as indicated by the divergent subject matter and different classification. For instance a search of the prior art to Group II would not reveal prior art of Groups I and III-XIII as indicated by their different classification. Further with regards to the traversal on the ground that it would not be a serious burden to search all Groups it is the Examiner's position that the search for each of the above inventions is not co-extensive particularly with regard to the literature search. A reference which would anticipate the invention of one group would not necessarily anticipate or make obvious any of the other groups. Consequently, claims 1-97 are pending in the instant application, of which claims 1-7 and 26-97 are withdrawn from further consideration.

The requirement is still deemed proper and is therefore made FINAL.

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***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claims 8-13 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 8-13 are directed to a nucleic acid sequence, has the same characteristics and utility as the nucleic acid sequence found naturally and therefore does not constitute as patentable subject matter.

In the absence of the hand of man, naturally occurring products are considered non-statutory subject matter. Diamond v. Chakrabarty, 206 USPQ 193 (1980). Mere purity of naturally occurring product does not necessarily impart patentability. Ex parte Siddiqui 156 USPQ 426 (1966). However when purity results in new utility, patentability is considered. Merck Co. V. Chase Chemical Co. 273 F. Supp 68 (1967). See also American Wood v. Fiber Disintergrating Co., 90 US 566 (1974); American Fruit Growers v. Brogdex Co. 283 US 1 (1931); Funk Brothers Seed Co. V. Kalo Innoculant Co. 33 US 127 (1948). Filing of evidence of a new utility imparted by the increased purity of the claimed invention and amendment to the claims to recite the essential purity of the claimed products is suggested to obviate this rejection. For example, "An isolated nucleic acid sequence..."

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***Claim Rejections - 35 USC § 112***

3. Claims 11-13, 17, 21, and 25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims 11-13, 17, 21, and 25 recite nucleic acid sequences with no greater than about a 15% mismatch under stringent conditions in reference to SEQ ID NO: 2.

The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. Thus, the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, SEQ ID NO: 2 alone is insufficient to describe the genus. Thus, Applicant's have not described a function which is shared by SEQ ID NO: 2 which would adequately describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The protein itself is required. See

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*Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 “Written Description” Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

4. Claims 10-13, 16-17, 20-21, and 24-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are vague and indefinite in the recitation of “substantially hydrophobic domain.” One of skill in the art would be unable to determine the metes and bounds of the claimed invention. For instance, what degree of hydrophobicity is required to be “substantially hydrophobic?” Likewise at what point is substantially hydrophobic no longer attained? Without a clear definition as to the metes and bounds of substantially hydrophobic, one of skill in the art would be unable to practice the broadly claimed invention.

5. Claims 10-13, 16-17, 20-21, and 24-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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The claims are vague and indefinite in the recitation of “at least 31 amino acids carboxyl to the motif” and “residues 31-33 from the motif.” One of skill in the art would be unable to determine the metes and bounds of the claimed invention. For instance, does the sequence numbering begin with the motif, the center of the motif, or the end of the motif? Without a clear definition as to the where to start counting amino acid residues, one of skill in the art would be unable to practice the broadly claimed invention.

6. Claims 11-13, 17, 21, and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are directed to a polynucleotide complementary to SEQ ID NO: 2 under “stringent conditions.” Possibilities for hybridization are determined by the stringency of the procedure. Stringency, determined by the physical and chemical conditions, establishes the degree of hybridization. Without a clear definition as to the physical and chemical conditions as well as that of the wash step encompassed within “stringent conditions” one of skill in the art would be unable to replicate the claimed invention since the metes and bounds are not pointed out.

7. Claims 8-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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The claims are vague and indefinite in the recitation of “substantially purified” sortase-transamidase. One of skill in the art would be unable to determine the metes and bounds of such a limitation. For instance, what level of purification would constitute as “substantially?” Without a clear definition as to the degree of purification which would constitute as “substantially” one of skill in the art would be unable to replicate the claimed invention.

8. Claims 11-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are vague and indefinite in the recitation of “greater than about.” One of skill in the art would be unable to determine the metes and bounds of the limitations. The courts have held that claims reciting “at least about” were invalid for indefiniteness where there was close prior art and there was nothing in the specification, prosecution history, or the prior art to provide any indication as to what range of specific activity is covered by the term “at least about.” (Amgen v. Chugai Pharmaceutical Co. Ltd., 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991)).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 11-13, 17, 21 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Kunsch et al.

The claims are directed to a nucleic acid sequence which hybridizes to SEQ ID NO: 2 or a sequence complementary to SEQ ID NO: 2 with no greater than about a 15% mismatch under stringent conditions.

Kunsch et al (EP 786519) disclose of polynucleotides, vectors, host cells and methods of expression of polynucleotides obtained from *Staphylococcus aureus*. Kunsch et al further set forth of SEQ ID NO: 538 which is 98.4 % identical to SEQ ID NO: 2 of the instant invention.

In view that Kunsch et al disclose of a polynucleotide, vector, host cell and methods of expression of the polynucleotide obtained from *Staphylococcus aureus* which is 98.4 % identical to SEQ ID NO: 2 of the instant invention, the disclosure of Kunsch et al is deemed to anticipate the claimed invention.

***Double Patenting***

10. Claims 9, 15, 19, and 23 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 8, 14, 18 and 22. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is

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proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). In view of the restriction requirement only nucleic acids encoding SEQ ID NO: 3 are under consideration, consequently these claims are deemed to have the identical limitations.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro, whose telephone number is (703) 306-3225. The examiner can be reached on Monday - Thursday from 8:00 AM - 6:00 PM. The examiner can be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Lynette Smith can be reached at (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1645 by facsimile transmission. Papers should be faxed to Group 1645 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the official Gazette 1096 OG 30 (November 15, 1989). The CMI Fax Center number is (703) 308-4242.



Mark Navarro

Primary Examiner

July 19, 2001